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From: Stevenson, Allan (DPH)
Sent: Monday, January 30, 2006 11:47 AM
To: Salemi, Charles (DPH)
Subject: FW: January 2006 QC Meeting

Hi Chuck,

I guess the phones aren't working. Can I make a suggestion about item 1.d)? The autotune sheet generated by the GC/MS is already dated, also the point of running the autotune is to determine if the MS is working properly, in addition we run standards to confirm that the GC/MS is continuing to function correctly. I can see having the analyst who runs the autotune initial the run and writing "OK" or "shut down for maintenance " on the autotune sheet, but I think creating another form is redundant and creates a possible source of transcription errors as described in item 1.g). What do you think?
Also lets talk about item 4, perhaps we can come up with a way for the computer to track this rather than creating more forms and journals.

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From: Piro, Peter (DPH)
Sent: Friday, January 13, 2006 6:18 PM
To: George, Harvey (DPH); DiNatale, Margaret (DPH); Tisei, Nancy (DPH); Salemi, Charles (DPH); Piro, Peter (DPH)
Cc: Stevenson, Allan (DPH); Caloggero, Dina (DPH)
Subject: January 2006 QC Meeting

Present: Dr. George, Margaret DiNatale, Nancy Tisei, Charles Salemi, and Peter Piro
Minutes: Prepared by Peter Piro

1. Review of December QC

a) The balance QC was checked and signed off by Dr. George.

b) The UV/VIS spectrophotometer QC was reviewed and signed off by Nancy Tisei. The linearity check will not be performed since quantitations are no longer routinely performed on the UV/VIS instrument. The QC sheet will be restructured to reflect this change.

c) The IR spectrophotometer QC was reviewed and signed off by Margaret DiNatale. New QC sheets will be submitted to QA for the old and new IR instruments at the next meeting.

d) The GC/MS autotune reports were reviewed by Margaret DiNatale. QA will not sign off until operators initial and date autotunes. Dr. George requested that the Drug lab also come up with a QA form that summarizes the suitability of each instrument prior to use. The Drug Lab will submit this form at the next QC meeting for review along with other internal QC forms for this process.

e) The weekly QC test mix sheet for the GC/MS instruments was checked and signed off by Nancy Tisei. This form will add cocaine/codeine abundances to evaluate injector suitability.

f) The reagent preparation book was reviewed and signed off by Nancy Tisei.

g) The QC paperwork for GC/MS qualitative standards was reviewed and signed off by Margaret DiNatale. Dr. George noted too many sheet existed that were not original QC copies. To reduce the possibility of transcriptional errors, the Drug Lab will not submit an excel summary of prepared standards for the month, thereby eliminating the intermediary form used in data entry. Our two existing QC forms will be retained and a new QA summary form will be created. All forms will be submitted at the next meeting along with an explanation of the process.

2. Written results for the December sample audit were submitted and signed off by Margaret DiNatale.

3. Amherst Lab QC records were checked and signed off by Margaret DiNatale.

4. No review of corrected certificates issued since September 2005 was possible. A more detailed quality control program for the office will be instituted in the next few months.

5. 2005 refrigerator temperature charts were reviewed and signed off by Nancy Tisei.

6. Equipment maintenance records for July-December 2005 were reviewed and signed off by Dr. George, Nancy Tisei and Margaret DiNatale.

7. The Drug Lab QA study project for 2006 will focus on better documenting GC/MS QC procedures. We will review and where needed improve QC procedures. It is also the goal of the Laboratory to write SOP for the GC/MS Laboratory and for specialty samples.